

### **Remarks**

Claims 1-7 and 9-34 are presently pending in the subject application. Claim 8 has been canceled herein without prejudice or disclaimer.

Reconsideration and allowance in view of the above amendments and the following remarks are respectfully requested.

Claims 1 and 21 have been amended herein to more precisely indicate the order of the steps being performed and to indicate that the collection device is sealed. Claim 1 has been further amended to substantially incorporate the limitation of canceled claim 8.

Claims 4-7, 10, 13, 15, 16, 18, 24-28 and 30 have been amended herein consistent with the amendments to claims 1 and 21.

Claims 33 and 34 are new. Claim 33 depends from claim 21 and recites that the speed of the fluid transfer device increases as it enters the collection device to at least twice the speed of the fluid transfer device when it punctures the cap. Claim 34 depends from claim 33 and recites that the speed of the fluid transfer device when it punctures the cap is from about 15 mm/s to about 60 mm/s. Support for new claims 33 and 34 can be found in the specification at, for example, page 35, lines 12-16.

### **Interview Summary**

On July 1, 2008, Applicants' representative participated in a telephonic interview the Examiner and Supervisory Patent Examiner Walter Griffin. Applicants thank the examiners for the many courtesies that were extended to Applicants' representative during the interview. The above amendments and the following response to the Examiner's rejections under 35 U.S.C. § 102(b) and 103(a) fully set forth the particulars that were discussed during the interview.

### **Prior Art Rejections**

The claims stand rejected under Sections 102(b) and/or 103(a) as being anticipated by Collier *et al.* (U.S. Pat. No. 5,130,254) or unpatentable over Collier, alone or in combination with any one

or more of Köster *et al.* (International Publication No. WO 00/60361), Seto (U.S. Pat. No. 5,874,048), Sandhage (U.S. Pat. No. 2,906,423), Koch (U.S. Pat. No. 5,578,272), Levy (U.S. Pat. No. 6,054,099). Applicants respectfully traverse these rejections for the reasons that follow.

The Examiner contends that Collier discloses the method of claim 1, including the steps of pausing the movement of the fluid transfer device prior to contacting a fluid substance contained in the vessel and then continuing movement of the fluid transfer device until it contacts the fluid substance. Although the Examiner indicates that claim 1 does not require that the recited steps be performed in any particular order, Applicants' representative noted during the interview that step c) of claim 1 requires that the pause step be introduced prior to contacting the fluid transfer device with the fluid substance. Notwithstanding, Applicants have amended claim 1, as agreed to with the Examiner, to recite that the steps of the method must be performed in the specific order recited.

Introducing a pause step prior to contacting a fluid substance contained in a closed vessel is nowhere disclosed or suggested by Collier. While Collier recognizes the benefits of venting air from a sealed container, the approach disclosed by Collier is to move a probe 14 downward through a lid 12 of a container 10, and to continue this downward movement uninterrupted until the probe is immersed in a fluid substance held by the container (*i.e.*, just before the tip 34 of the sleeve 22 touches the lid 12). *See* Collier at col. 4, lines 23-36; *see also* Figure 2B. Once immersed in the fluid substance, the downward movement of the probe 14 is stopped and the probe is moved laterally to stretch an elastomeric portion of the lid 12, thereby permitting air to be released from the container 10. *See* Collier at col. 4, lines 37-43. There also would have been no motivation for introducing a pause step into the method of Collier, as the lid 12 of Collier is an elastomeric material that forms around the probe 14, which is the reason for stretching the lid 12 with the probe 14. Thus, but for the stretching step after fluid contact, air would not be vented from Collier's container 10.

The Examiner further contends that the method of claim 21, with its requirement that the speed of the fluid transfer be increased after the cap of the collection device has been punctured, would have been obvious since this solves the problem identified by Collier, which is to equilibrate the pressure within the container 10 with the atmospheric pressure. *See* Collier at col. 4, lines 39-43. The Examiner provides no support for this argument other than to state that “the slower speed is essential to allowing the pressure from inside of the container to equilibrate with the pressure of the environment.” *See* Office Action at page 15, lines 8-11 (emphasis added). Collier, however, provides no suggestion that the speed of the probe 14 is in any way critical to the controlling pressure within the container 10 during the downward movement of the probe. (As noted above, Collier’s solution is to move the probe 14 laterally to stretch the lid 12.) Additionally, since the portion of the lid 12 penetrated by the probe 14 of Collier is elastomeric, the lid will have a tendency to conform to the shape of the probe. Thus, skilled artisans in possession of Collier would not have concluded that changing the speed of the probe 14 would effect the pressure within the container 10.

Applicants submit that the Examiner’s reasoning is unsupported by the facts and constitutes impermissible hindsight reconstruction. *See* MPEP § 2143.01 at 2100-140 (Rev. 6, Sept. 2007) (“[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.”) (Citing *KSR*, 550 U.S. at \_\_\_, 82 USPQ2d at 1396 quoting *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006).) Further, substituting Applicants’ claimed method for venting air from a closed container for that of Collier would render Collier’s method for accessing the contents of a container 10 unworkable, as the elastomeric lids 12 of Collier tend to conform to the shape of the probe 14, leaving no space for the formation of air passageways that would facilitate the venting of air from the containers). *See* MPEP § 2143.01 at 2100-140 (Rev. 6, Sept. 2007) (“If proposed modification would render the prior art being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification.”.) (Citing *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).)

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None of the secondary references cited by the Examiner overcome the deficiencies of Collier. Thus, for the reasons set forth above, Applicants submit that the presently pending claims are fully patentable in view of the cited references, whether considered alone or in any combination. Accordingly, withdrawal of the Examiner's prior art rejections is hereby respectfully requested.

**Conclusion**

Based on the above amendments and remarks, Applicants submit that the presently pending claims are in condition for allowance and notice to that effect is hereby respectfully requested.

Please charge any fees due in connection with this Reply, including the excess claims fee due under 37 C.F.R. § 1.16(j), to Deposit Account No. 07-0835 in the name of Gen-Probe Incorporated.

Respectfully submitted,

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